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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/688,551

10/17/2003

Indranil Nandi

G-33422P1/GPI

1169

72554

7590

02/17/2009

SANDOZ INC  
506 CARNEGIE CENTER  
PRINCETON, NJ 08540

EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

02/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/688,551 | <b>Applicant(s)</b><br>NANDI ET AL. |  |
|                              | <b>Examiner</b><br>Carlos A. Azpuru  | <b>Art Unit</b><br>1615             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Receipt is acknowledged of the amendment filed 12/22/2008.

The rejection under 35 USC 103(a) over Holt et al is withdrawn in view of applicant's amendment.

The following rejection is made in view of applicant's amendment:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4,5, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holt et al (S Patent No. 6,740,341) in view of Mukherji et al (US Patent No. 6,565,877).

Holt et al discloses a taste masking formulation comprising a core containing the drug, a taste masking layer, and a spacing layer around the core sequestering it from the taste masking layer (see Abstract; col. 2, lines 15-37). The inner “spacing layer” comprises ethyl cellulose, methyl cellulose, hydroxypropyl cellulose or hydroxy propyl methyl cellulose (see col. 5, lines 65-67; col. 6, line 1). Antibiotics are among the drugs which need taste masking as shown at col. 3, line 64. The enteric layer may be aminoalkyl methacrylate copolymer (see col. 6, lines 40-41). Coated particle size range may be up to 850 microns (col. 7, lines 19-24). Taste masking and spacer layer thickness are both disclosed as between 5 and about 75 microns (see claim 1). The core drug particles would therefore fall within the claimed size parameters, given that the core size must fall within the maximum limitations of the coated particle, minus those of the two coatings. Holt et al sets out multiple drug particles in the core at col. 7, lines 8-10. Amount of drug (antibiotic) is disclosed as between 0 and 60% at col. 5, lines 1-3. Disintegrable tablets are disclosed at col. 8, line 45. Holt et al differs from the instant claims in that copolymers of methacrylic acid and methyl methacrylate or methacrylic acid and ethyl acrylate are not specifically recited. However, along with Eudragit E100, Holt et al states, “any material which can meet these objectives is specifically contemplated.” (see col. 6, lines 38-39).

Mukherji et al specifically sets out a taste masking composition of methacrylic copolymers(see Abstract). Copolymers of methacrylic acid and methyl methacrylate or methacrylic acid and ethyl acrylate are specifically disclosed for this purpose at col. 2,

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lines 48-62. particles in suspension are set out in claim 35 of Mukherji et al. Therefore, those of ordinary skill would have found it well within their skill to select an antibiotic as the drug which requires taste masking, and further to coat this core with two layers as taught by Holt et al , with the modification being an outer coating comprising copolymers of methacrylic acid and methyl methacrylate or methacrylic acid and ethyl acrylate as instantly claimed for the same art recognized purpose of taste masking and enteric drug delivery as suggested Mukherji et al. Therefore, those of ordinary skill would have further expected similar taste masking and therapeutic results from the instant formulations given the disclosure of Holt et al. in view of the taste masking properties of copolymers of methacrylic acid and methyl methacrylate or methacrylic acid and ethyl acrylate as taught by Mukherji et al. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the disclosures of Holt et al in view of Mukherji et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615

Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

caz